

## PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : KUMAR, Vijay  
SERIAL NO : 10/007,866  
FILED : December 6, 2001  
TITLE : BIODEGRADABLE OXIDIZED CELLULOSE ESTERS

Grp./A.U. : 1623  
Examiner : White, E.  
Conf. No. : 6560  
Docket No. : P04829US1

OFFICIAL

## RULE 132 DECLARATION OF DR. VIJAY KUMAR

RECEIVED  
CENTRAL FAX CENTER  
OCT 24 2003

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Sir:

I, Dr. Vijay Kumar, hereby declare the following:

1. I am a co-inventor of the invention set forth in Serial No. 10/007,866.
2. I have obtained bachelor of science degrees in chemistry, zoology, and botany from Kanpur University in India. I received a master of science degree in chemistry from Lucknow University in 1972, and a Ph.D. degree in chemistry from Lucknow University in 1976, and another Ph.D. from Concordia University in Montreal in 1981. My postdoctoral work has been in the areas of pharmaceuticals and chemistry.
3. From 1992-1996, I was a clinical assistant professor professor and from 1996-2002 an assistant professor in the pharmaceuticals division of the College of Pharmacy, University of Iowa. From 2002 to present I have been an associate professor of the pharmaceuticals in College of Pharmacy, University of Iowa.

4. I have conducted and supervised numerous pharmaceutical research projects since 1993. These projects have dealt primarily with pharmaceutical excipients and formulation techniques.

5. My current research has focused on carbohydrate polymers, especially cellulosic polymers, and their uses as pharmaceutical excipients, drug carriers, and biomaterials, biodegradable delivery systems, tissue engineering, interpolymer complexes, and drug-excipients.

6. I understand that the Examiner has rejected claims 1-12 under 35 U.S.C. 102(b) as being anticipated by Diamantoglou et al. (U.S. Pat. No. 5,008,385). The Examiner's contention that the cellulose derivatives of Diamantoglou anticipate the oxidized cellulose esters of the claimed invention is incorrect.

7. Diamantoglou discloses cellulose esters. Diamantoglou does not, however, disclose oxidized cellulose esters, as claimed in the present invention.

8. The polymers listed in the Diamantoglou patent describe cellulose derivatives containing carboxylic acid groups that are not derived from cellulose but introduced in cellulose as part of substituents. In other words, the carboxylic acid groups in cellulose derivatives are not directly linked to the cellulose backbone, but instead are linked to the side chains (or substituents). This is in contrast to the oxidized cellulose esters of the claimed invention whereby the carboxylic acid groups are an integral part of the oxidized cellulose, the starting material used to prepare the esters of the claimed invention. The carboxylic acid groups in the cellulose backbone (at carbon six position) results from an oxidation reaction.

9. Because the carboxylic acid groups are not directly linked to the cellulose backbone, the water-insoluble, fibrous, cellulose esters of Diamantoglou are not biodegradable, and therefore not useful for the purposes of the claimed invention, which include use as film-forming agents, drug carriers, and immobilizing matrix in the development of biodegradable controlled and/or sustained release pharmaceutical, agricultural, and veterinary compositions. In fact, the cellulose derivatives of Diamantoglou are used primarily as fibers and membranes in hemodialysis. (Col. 1, lines 8-10).

10/23/03 08:17 FAX 3193359349

PHARMACEUTICS UIOWA

002

10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date:

10/23/03Vijay Kumar

Dr. Vijay Kumar

RECEIVED  
CENTRAL FAX CENTER

OCT 24 2003

OFFICIAL